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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,372	10/10/2003	Stig Ollmar	P08079US01/BAS	6095
881 7590 08/03/2009 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER NATNITHITHADHA, NAVIN	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 08/03/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/682,372

Applicant(s)

OLLMAR ET AL.

Examiner

NAVIN NATNITHITHADHA

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17 and 19-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Remarks, pp. 1-9, filed 20 April 2009, with respect to the rejection of claims 14-17 and 19-43 under 35 U.S.C. 103(a) as being unpatentable over Davies et al, U.S. Patent No. 6,922,586 B2 ("Davies") in view of Stemme et al, U.S. Patent Application Publication No. 2004/0054393 A1 ("Stemme"), have been fully considered, but they are not persuasive.

Applicant contends, see Remarks, pp. 1-9, the following as to how Davies is distinguishable from Applicant's disclosed invention:

...one of ordinary skill in the art would not have seen any benefit from altering the device of Davies to incorporate the electrode of Stemme to in any way arrive at the claimed invention.

In contrast to the present invention in which the present apparatus and technique determine a diseased condition using impedance values measured at specific locations of a patients skin, Davies discloses a method and apparatus for detecting abnormal tissue by measuring transport alterations in mucosal tissues.

...one would not modify the disclosure of Davies to incorporate aspects of the device of Stemme in that Stemme is directed to a completely different method/technique from that of Davies.

....it would be clear that the one of ordinary skill in the art would not have combined the diagnostic technique and device of Davies with the electrode and technique to measure biopotentials of Stemme to arrive at the claimed invention.

However, these arguments are not persuasive.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Davies' electrode structure with Stemme's electrode structure because Davies suggests the following:

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Alternatively, surface electrodes that just penetrate the stratum corneum may be used to decrease impedance. See col. 10, ll. 58-59.

In one embodiment, electrophysiological measurements are performed using a series of two or more electrodes attached to an examining glove or probe. Some factors influencing the spacing of the electrode and the signal used include the depth of penetration desired and permeabilization of the surface epithelium using penetrating agents. A probe that permits variable frequency signals and varying electrode placement provides the most versatile arrangement, but a probe or glove providing a single frequency signal and/or static electrode placement may also be used. See col. 13, ll. 55-65.

Applicant's arguments, in regard to the Davies' combinability to electrode structures that can penetrate the stratum corneum is not persuasive because of the explicit suggestion above by Davies.

In addition, Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, Applicant states advantages of these features over Davies and Stemme, but did not cite any evidence to support these allegations.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 14-17 and 19-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies in view of Stemme et al, U.S. Patent Application Publication No. 2004/0054393 A1 ("Stemme").

Claims 14-17 and 19-29: As to claims 14-16, 19-21, and 27-29, Davies teaches a method for diagnosing a diseased condition of the skin (see Abstract and figs. 1-4), the method comprising the steps of:

(i) placing an electrical conducting probe ("probe device") 105/400 against a skin surface of the subject (see fig. 4A), wherein the probe 105/400 comprises a plurality of electrodes (see fig. 3), wherein a first electrode ("current passing electrodes") 5 and a second electrode (first ring of "voltage sensing electrodes") 8 of the plurality of electrodes are spaced a first distance from each other and wherein the first electrode 5 and a third electrode (second, inner ring of "voltage sensing electrodes") 8 of said plurality of electrodes are spaced a second distance from each other;

(ii) passing an electrical current through the electrodes to obtain a value of skin impedance, wherein said electrical current is separately passed between the first

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electrode 5 and the second electrode (first ring of "voltage sensing electrodes") 8 and between the first electrode 5 and the third electrode (second, inner ring of "voltage sensing electrodes") 88 to obtain at least a first value of impedance and at least a second value of impedance (see fig. 3 and col. 11, ll. 36-44, and col. 11, l. 64, to col. 12, l. 12); and

(iii) using reference data to determine whether the impedance value indicates the diseased condition, such as skin cancer (see col. 8, ll. 60-65, col. 9, ll. 48-65, col. 9, l. 66, to col. 10, l. 19, and col. 11, ll. 1-4).

Davies does not teach "each electrode furnished with a number of spikes, the spikes being laterally spaced apart from each other and being of sufficient length to penetrate the stratum corneum" in claim 1, along with the subject matter of claims claims 17 and 22-26, which directed to the amount and dimensions of the spikes. However, Stemme teaches a "medical electrode... comprises a base that includes an array of micro-dimensioned spikes designed to pierce the outer skin layer, i.e. the stratum corneum and penetrate into the electrically conductive stratum germinativum, thereby to circumvent the high impedance characteristics of the stratum corneum SC" (see para. 28). "The spikes are long enough to reach the stratum germinativum and are able to carry an electrical signal" (see para. 12). In addition, Stemme teaches the following (see para. 29):

However, the spikes must not reach the tissue layer below the stratum germinativum containing nerves and blood vessels so as to avoid pain or bleeding of the subject. The thickness of the stratum corneum is approximately 10 to 15 .mu.m. The thickness of the stratum germinativum is about 50 to 100 .mu.m. Thus, spikes that penetrate the skin more than 10-15 .mu.m, but less than about 50-100 .mu.m, produce a pain-free

electrode-electrolyte interface at the stratum germinativum and transform the ionic current induced by active cells into an electronic current. To achieve this, experiments have shown that the spike length of a majority of the spikes in the array should be in the range of 150 to 350 .mu.m, possibly as long as 500 .mu.m.

Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Davies' electrode structure with Stemme's electrode structure because Davies suggests the following:

Alternatively, surface electrodes that just penetrate the stratum corneum may be used to decrease impedance. See col. 10, ll. 58-59.

In one embodiment, electrophysiological measurements are performed using a series of two or more electrodes attached to an examining glove or probe. Some factors influencing the spacing of the electrode and the signal used include the depth of penetration desired and permeabilization of the surface epithelium using penetrating agents. A probe that permits variable frequency signals and varying electrode placement provides the most versatile arrangement, but a probe or glove providing a single frequency signal and/or static electrode placement may also be used. See col. 13, ll. 55-65.

Applicant's arguments, in regard to the Davies' combinability to electrode structures that can penetrate the stratum corneum, see Request for Reconsideration After Final, p. 4, filed 08 August 2008, is not persuasive because of the explicit suggestion above by Davies.

Claims 30-43: Because Applicant stated that the added new apparatus claims 30-43 correspond to method claims 14-17, 19-27, and 29, respectively, and are not independent and distinct inventions, the claims 30-43 are rejected for the same reasons as stated above for claims 14-17, 19-27, and 29.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. N./
Patent Examiner, Art Unit 3735
07/23/2009

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735